OCT - 3 2001

ATTACHMENT 4

510(k) Summary

Date July 23, 2001

Contact Greg Alkire
Director, Regulatory Affairs
Medical Data Electronics
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Arleta, California 91331
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Device Name ESCORT® Vision Central Station with Stickman Telemetry Transmitter

Common Name Central Station Monitor
Detector and Alarm, Arrhythmia

Cardiac Monitor
RF Physiological Transmitter/Receiver

Classification The classification names and classifications of the ESCORT® Vision Central Station with Stickman Telemetry Transmitter are as follows:

Device	Classification Number	Class
Arrhythmia Detector and Alarm	870.1025	III
Cardiac Monitor	870.2300	II
RF Physiological Transmitter/Receiver	870.2910	II

Predicate Device	ESCORT Vision Central Station, 510(k) K982104, clearance date: November 25, 1998 and the ESCORT Guardian, Model 20601, 510(k) K961138, clearance date: July 14, 1997
Device Description	The modified ESCORT Vision Central Station is a central station monitor comprised of a standard VGA display, a standard personal computer base and an auxiliary base or receiver hub used to mount the network communications hardware. The modified Stickman telemetry transmitter is an RF physiological signal transmitter comprised of an ECG measurement system packaged with a UHF transmitter. The modified ESCORT Vision Central Station provides centralized display, storage and recording (or printing) of patient vital sign and waveform data that are being monitored at ESCORT II, 100, 300 or 400 Series Bedside Monitors or UHF telemetry receivers. The modified Stickman telemetry transmitter provides ECG signal monitoring and RF signal transmission. The modified ESCORT Vision Central Station with Stickman Telemetry Transmitters communicates in the new WMTS band, providing protection against interference.
Indications For Use	The ESCORT Vision Central Station is intended to be used to provide, using a wireless LAN for communication, centralized surveillance and documentation of patient vital sign data and arrhythmia/ST monitoring for a variable number of ESCORT II Bedside Monitors and a variable number of UHF telemetry transmitters in the hospital environment. It is intended for use by healthcare practitioners trained in the use of the equipment only. The ST algorithm has been tested for accuracy of the ST segment measurement data. The significance of the ST segment changes must be determined by a physician.
Technological Characteristics	The modified ESCORT Vision Central Station with Stickman Telemetry Transmitter has the same technological characteristics as the predicate device. Additional software is added to facilitate the channel and identifier programming capability for Stickman telemetry transmitters configured for WMTS.

Testing Testing of the modified ESCORT Vision Central Station with Stickman Telemetry Transmitter is being conducted by MDE to ensure mitigation of hazards. V&V testing and testing of the modified device to safety standards include the same ones as performed on the predicate devices with tests added to address issues raised as a result of the new hazard analysis.

Conclusions Medical Data Electronics, in accordance with the FFDCA and 21 CFR Part 807 and data included in this premarket notification, concludes that the modified ESCORT Vision Central Station with Stickman Telemetry Transmitter is safe, effective and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2001

Mr. Greg R. Alkire
Director of Regulatory Affairs
Medical Data Electronics
12723 Wentworth St.
Arleta, CA 91331

Re: K012336
Trade Name: ESCORT Guardian
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class III (three)
Product Code: 74 DSI
Dated: September 21, 2001
Received: September 24, 2001

Dear Mr. Alkire:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 2

Indications for Use Statement

510(k) Number (if known): K012336

Device Name: ESCORT Vision Central Station

Indications for Use:

The ESCORT Vision Central Station is intended to be used to provide, using a wireless LAN for communication, centralized surveillance and documentation of patient vital sign data and arrhythmia/ST monitoring for a variable number of ESCORT II Bedside Monitors and a variable number of UHF telemetry transmitters in the hospital environment. It is intended for use by healthcare practitioners trained in the use of the equipment only.

The ST algorithm has been tested for accuracy of the ST segment measurement data. The significance of the ST segment changes must be determined by a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012336

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)